

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 4299
OFFERED BY M . _____**

Strike all that follows after the enacting clause, and
insert the following:

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the “Improving Regulatory
3 Transparency for New Medical Therapies Act”.

**4 SEC. 2. SCHEDULING OF SUBSTANCES INCLUDED IN NEW
5 FDA-APPROVED DRUGS.**

6 Section 201(a) of the Controlled Substances Act (21
7 U.S.C. 811(a)) is amended by adding at the end the fol-
8 lowing: “Any such proceedings initiated at the request of
9 the Secretary under this subsection to control a drug or
10 other substance not previously scheduled, where the Sec-
11 retary has recommended the drug or other substance be
12 placed in schedule II, III, IV, or V, shall be commenced
13 not later than 120 days after receipt of written rec-
14 ommendations from the Secretary. The final rule shall be
15 issued not later than 60 days after the date on which both
16 the public comment period has closed and the drug or
17 other substance is the subject of an approved new drug
18 application under section 505 of the Federal Food, Drug,

1 and Cosmetic Act, unless a hearing on the proposed rule
2 is granted by the Attorney General.”.

3 **SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.**

4 Section 303 of the Controlled Substances Act (21
5 U.S.C. 823) is amended by adding at the end the fol-
6 lowing:

7 “(i)(1) For the purposes of registration to manufac-
8 ture a controlled substance under subsection (d) of this
9 section for use only in a clinical trial, the Attorney General
10 shall register an applicant or serve an order to show cause
11 upon an applicant pursuant to section 304(c) of this Act
12 not later than 180 days after receipt of an application and
13 all information the Attorney General deems necessary to
14 make a determination under subsection (d).

15 “(2) For the purposes of registration to manufacture
16 a controlled substance under subsection (a) for use only
17 in a clinical trial, the Attorney General shall, in accord-
18 ance with regulations issued by the Attorney General,
19 issue a notice of application not later than 90 days after
20 receipt of an application and all information the Attorney
21 General deems necessary to issue a notice of application.
22 Following the close of the comment period and receipt of
23 all information the Attorney General deems necessary to
24 make a determination under subsection (a), the Attorney
25 General shall register an applicant or serve an order to

1 show cause upon an applicant pursuant to section 304(c)
2 of this Act within 180 days, unless a hearing on the appli-
3 cation has been granted by the Attorney General pursuant
4 to section 1008(i) of the Controlled Substances Import
5 and Export Act.”.

